IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9145

Bartle, J. September 20, 2013

Frances A. Pugh ("Ms. Pugh" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement §§ IV.B.1.a. & I.22.

In October, 2009, claimant submitted a completed Green Form to the Trust signed by her attesting cardiologist, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Based on an

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

echocardiogram dated January 23, 2003,[3] Dr. Evans attested in Part II of claimant's Green Form that Ms. Pugh suffered from moderate aortic regurgitation and aortic dissection involving the aortic root and/or aortic valve.[4] Dr. Evans also attested that claimant had valvular repair or replacement surgery and required a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery.[5] Based on such findings, claimant would be entitled to Matrix B-1, Level IV benefits in the amount of $93,498.[6]

In the report of claimant's February 4, 2002 echocardiogram, the reviewing cardiologist, Philip Madaelil, M.D., stated that claimant had mild aortic

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3. Because claimant's January 23, 2003 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated February 4, 2002 to establish her eligibility to receive Matrix Benefits.

4. The presence of aortic dissection involving the aortic root and/or aortic valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(c)i)b).

5. In addition, Dr. Evans attested that claimant suffered from a reduced ejection in the range of 50% to 60% and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she "had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery." See Settlement Agreement § IV.B.2.c.(4)(g).

insufficiency.[7] Dr. Madaelil, however, did not specify a percentage as to claimant's level of aortic regurgitation. Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In December, 2009, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for the attesting physician's finding of mild aortic regurgitation. Dr. Gradus-Pizlo explained, "There is no aortic regurgitation. On one Doppler image there is an attempt to measure mitral inflow as demonstration of aortic regurgitation."

Based on the auditing cardiologist's finding that claimant did not have at least mild aortic regurgitation, the Trust issued a post-audit determination denying Ms. Pugh's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims

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7. Claimant also submitted an echocardiogram report prepared in June, 2003 by Dr. Evans based on her February 4, 2002 echocardiogram. In this report, Dr. Evans stated that claimant had mild aortic regurgitation with a JH/LVOTH ratio of 15%.

("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant argued that there was a reasonable medical basis for finding at least mild aortic regurgitation based on her February 4, 2002 echocardiogram because the original reviewing cardiologist found mild aortic regurgitation "in the ordinary course of medical practice." In addition, claimant submitted an affidavit of Dr. Evans, wherein he stated, in pertinent part, that:

> The Trust auditor was wrong in finding that claimant's echocardiogram tape of 02/04/2002 does not show any aortic regurgitation. In fact, it shows "mild" aortic regurgitation. The JH/LVOTH ratio is 15% and this is best seen at about 2:25 into the recording. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that this echocardiogram tape shows "mild" aortic regurgitation when answering Question C.3.b. in Part II of the Green Form.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Gradus-Pizlo submitted a declaration in which she confirmed that there was no reasonable medical basis for finding that claimant's February 4, 2002 echocardiogram demonstrated at least mild aortic regurgitation. Specifically, Dr. Gradus-Pizlo stated, in pertinent part, that:

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Pugh's claim.

> I find that Claimant's Contest Materials fail to establish a reasonable medical basis for [the] representation that claimant's February 4, 2002 eligibility echocardiogram demonstrates mild aortic regurgitation. There is no aortic regurgitation seen on this study, which includes a very thorough evaluation of [the] aortic valve, with multiple spectral Doppler tracings done from multiple views. Even with a Nyquist setting as low as 39 cm/sec, however, there is not even a trace of aortic regurgitation.
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> As I noted at the time of audit, on one Doppler image at the very end of the study, a faint mitral inflow signal is interpreted as measurement of [the] aortic regurgitation slope. This is done despite the fact that the measured velocities were between 1.8 and 1.2 m/sec, which is not compatible with velocities of aortic regurgitation, expected to be in the range of above 4m/sec.[9]

The Trust then issued a response to claimant's contest and an amended post-audit determination, again denying the claim. Following claimant's contest of Dr. Gradus-Pizlo's amended determination with respect to whether Ms. Pugh had a second surgery through the sternum within eighteen months of her initial surgery, the Trust issued a final post-audit determination, again denying Ms. Pugh's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

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9. Dr. Gradus-Pizlo also stated that she incorrectly determined at audit that claimant had a second surgery through the sternum within eighteen months after her initial surgery. Given our determination as to Ms. Pugh's eligibility to receive Matrix Benefits, we need not determine this issue.

show cause why the claim should be paid. On August 19, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8518 (Aug. 19, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2010. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that she suffered from at least mild aortic regurgitation between the commencement of Diet

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for such a finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for such finding, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Pugh repeats the arguments she made in contest, namely, that there is a reasonable medical basis for finding that her February 4, 2002 echocardiogram demonstrated mild aortic regurgitation because Dr. Evans and Dr. Madaelil agreed with such finding. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and that of the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of between 10% and 15% when evaluating aortic regurgitation. Thus, Ms. Pugh contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the JH/LVOTH ratio is as low as 10%, a finding of a 25% JH/LVOTH ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the claimant cannot meet her burden of proof simply by accumulating expert opinions. In addition, the Trust contends that Ms. Pugh is precluded from

raising her inter-reader variability argument in this stage of the proceedings because she did not seek nor receive permission to submit new evidence as part of her response.

The Technical Advisor, Dr. Abramson, reviewed claimant's February 4, 2002 echocardiogram and concluded that there was no reasonable medical basis for finding that Ms. Pugh had at least mild aortic regurgitation. Specifically, Dr. Abramson explained, in pertinent part, that:

> In reviewing the echocardiogram from 2/04/02, the parasternal windows are of suboptimal quality. In the parasternal long axis or short axis views, there is no evidence of aortic regurgitation. There is no aortic regurgitation visualized in the apical 3-chamber or apical 5-chamber views by color flow imaging, continuous wave Doppler or pulsed wave Doppler. If there were any aortic regurgitation, it would be seen on the spectral Doppler while pulsing the left ventricular outflow tract. There is no spectral Doppler evidence of aortic regurgitation. There are no measurements on the tape pertaining to aortic regurgitation. It is unclear what Dr. Evans meant by seeing the aortic regurgitation best at 2:25 into the study. There is no meter number that corresponds to 2:25. There is only 2D imaging without color flow or Doppler at 2 minutes 25 seconds into the study.
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> In summary, a reasonable echocardiographer would not interpret the severity of the aortic regurgitation on the echocardiogram of February 4, 2002 as mild. There is no aortic regurgitation on this study. There is no reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Frances A. Pugh has mild aortic regurgitation on the 2002 echocardiogram.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. In particular, Dr. Gradus-Pizlo reviewed claimant's February 4, 2002 echocardiogram and determined "[t]here is no aortic regurgitation." Although Dr. Evans contended that the JV/LVOTH ratio was 15% two minutes and twenty-five seconds into the tape, Dr. Gradus-Pizlo re-reviewed the study and confirmed there was "not even a trace of aortic regurgitation."[11] She noted that "a faint mitral inflow signal is interpreted as measurement of [the] aortic slope" but explained that the measured velocity was "not compatible with velocities of aortic regurgitation." Dr. Abramson also reviewed claimant's February 4, 2002 echocardiogram and determined there was no aortic regurgitation present, including two minutes and twenty-five seconds into the study. Specifically, Dr. Abramson noted, "There is only 2D imaging without color flow or Doppler at 2 minutes 25 seconds into the study."[12] Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any

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11. Claimant also relied on the reviewing cardiologist's conclusion that the echocardiogram demonstrated mild aortic regurgitation. Dr. Madaelil, however, did not specify a percentage as to claimant's level of aortic regurgitation.

12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

specific errors by them is insufficient to meet a claimant's burden of proof.

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Pugh had mild aortic regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the claimant does not adequately refute the determinations of the auditing cardiologist and Technical Advisor that Ms. Pugh did not have any aortic regurgitation. Adopting claimant's argument that inter-reader variability expands the range of a reduced ejection fraction by as much as ±15% would allow a claimant who does not have any aortic regurgitation to recover benefits. This result would render meaningless this critical provision of the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Pugh's claim for Matrix Benefits.